



**EU Declaration of Conformity
according to MDR**

Document ID: PD-710004 Rev:1
Created by: Emil Vestlund
State: Released
Approved by: Christina Lewing
Release date: 2022-07-06 13:20:58

Title: MDR DoC Mepitel One

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden, SRN SE-MF-000014042, being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Mepitel One
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Product Classification: MDR Class IIb
MDR Classification Rule: 4
Sterility: Sterile
Measuring Function: No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IX
Common Specification: No CS is applicable

Certificate number:	MDR 722028	
Issued by:	BSi	Id No: 2797
	(Notified Body Name)	
<i>NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.</i>		

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: 2022-07-06 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	Mepitel One is a wound contact layer designed for the management of a wide range of exuding wounds such as; skin tears, skin abrasions, surgical incisions, partial thickness burns, traumatic wounds, partial and full thickness grafts, radiated skin, leg and foot ulcers. It can also be used as a protective layer on non-exuding wounds, blisters and on areas with fragile skin.
Basic UDI-DI:	733243000000000022JJ
GMDN Code:	46855 Wound - nonadherent dressing, permeable

Product References Covered by this Declaration:	Product Descriptor:
289000	Soft silicone wound contact layer
289100	Soft silicone wound contact layer
289110	Soft silicone wound contact layer
289120	Soft silicone wound contact layer
289170	Soft silicone wound contact layer
289200	Soft silicone wound contact layer
289210	Soft silicone wound contact layer
289270	Soft silicone wound contact layer
289300	Soft silicone wound contact layer
289320	Soft silicone wound contact layer
289400	Soft silicone wound contact layer
289470	Soft silicone wound contact layer
289500	Soft silicone wound contact layer
289520	Soft silicone wound contact layer
289620	Soft silicone wound contact layer
289670	Soft silicone wound contact layer
289700	Soft silicone wound contact layer
289750	Soft silicone wound contact layer